REMARKS

These remarks are responsive to the Office Action of May 19, 2006. Claims 1- 74 have been rejected.

The specification has been amended in certain instances in order to correct typographical errors and ambiguities, and in order to provide up-to-date citations for cited U.S. patent applications which have now issued. In addition, in the interest of full disclosure, the specification has been amended to cite the issue patent number corresponding to U.S. Application No. 10/007,772, now U.S. Patent No. 7,072,725, having an inventor in common with the instant case.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to modify the computerized system of Engleson as being unpatentable over Engleson et al (U.S. Patent No. 5,781,442) in view of Vasko (U.S. Patent No. 5,871,465). The Applicant respectfully disagrees.

Engleson discloses a patient management system capable of monitoring, controlling, and tracking the administration of care in a *health care institution,* e.g., a hospital. Vasko discloses a communications infrastructure for the *real-time* monitoring and programming of an infusion system, especially one based on POTS, i.e., touch-tone telephony. There is no suggestion in either of the references that they be combined in the manner suggested by the Examiner. Absent such a suggestion, a person skilled in the art who was looking for a solution to the problems of tracking the administration of care in a health care institution as exhibited by Engleson would hardly be disposed on any objective basis, to consider a reference like Vasko, which is concerned only with providing one method among many of providing instructions to infusion devices and receiving feedback regarding present events such as alarm conditions.

Moreover, even if such suggestion to combine the teachings of Vasko and Engleson were present, nothing in the combination would yield a system according to the instant invention where communication with a drug pump manufacturer server provides a dynamic status prediction of events requiring pump explantation, that is, surgery to remove a drug pump for replacement or service. It is apparent that there is no desire on the part of Engleson or Vasko to predict pump failure at all. Instead, the disclosures of Engleson and Vasko assume that any "alarm conditions" (Engleson), or "alarms" (Vasko) can simply be dealt with by going to the

clinical device and clearing air-in-line, refilling medication, or replacing the infusion device at the patient bedside. In Engleson, the disclosure merely provides that a nurse may "quickly and easily identify the patient from the nursing station [module] and take appropriate action to address the condition causing the alarm." Engleson, col. 10, lines 5-8. Engleson makes no reference to implantable pumps, and Vasko's passing omnibus reference to subcutaneous pumps (Vasko, col. 17, line 41) is not to the contrary. While the instant invention certainly benefits from communication between an implanted pump and the rest of the system claimed, this communication is beneficial only as part of the monitoring necessary to improve the predictive power of the system as to when pump explantation is indicated; however, without the manufacturer database provided by the instant invention, such communication can only indicate when a pump has failed, resulting in an alarm condition. With an implanted device, this can typically be dealt with only by previously unplanned-for surgery. In contrast, the instant invention tends to reduce the risk and inconvenience of unplanned-for surgery and allows a user or physician to better predict and plan for any necessary surgery. In the disclosure of Engleson, such prediction is not necessary where a pump can be conveniently administered at a bedside machine by on-site caregivers.

While Vasko merely provides a remote-programming and communication system for drug pumps, Engleson discloses solely an institutional system for the maintenance and monitoring of infusion devices. To the extent that information is incorporated from sources outside the institution (for example by the *drug* manufacturer's supplied barcodes on unit dose packaging (Engleson col. 2, line 52-59), such information is static and thus fails to take into account the various changing data afforded by the present invention. The infusion device usage log, used to keep track of the preventative maintenance and calibration (i.e., accuracy of dispensing) of a device, can only be a historically-based, one-size-fits-all approach to infusion device maintenance, as it does not contemplate the incorporation of current device manufacturer data regarding drug shelf life, power requirements, device longevity, and the like, based on the device manufacturer's entirely empirical experience with a given device line. As mentioned earlier, there is no motivation in Engleson to do so, as the infusion device can be attended to on an ad hoc basis in response to device events, simply by dispatching a nurse to the patient's machine. Engleson displays no recognition of the problem of emergency surgery that would be

caused by the "just-in-time" (Engleson, col. 1, line 28) nature of the system disclosed, let alone any structure that would solve it.

Claim 1 has been amended to incorporate the limitations of previous claim 3. The invention of claim 1, as amended, provides for a communications environment for clinicians to directly access not only information pertaining to an implantable drug pump, but also integrate data from other data sources, such as pharmacies, therapeutic agent producers, implantable device manufacturers, other treatment providers, and the like. This gives direct connectivity between the patient, the implantable drug pump manufacturer, the physician, the pharmacist, and the implantable device surgeon with the implantable drug pump in a manner which minimizes explant surgery in a manner that does not subject the patient to undue risk from possible cessation of infusions. The structure that would result from the Examiner's proposed combination does not meet the terms of claim 1 as amended. Such claim recites several remote program code devices provided for a user, pertaining respectively to: the management of therapeutic substance infusion devices; reports detailing infusion device support and replacement management; and the communication of empirical device operation to the device manufacturer. By contrast, neither Engleson nor Vasko disclose communication with a drug pump manufacturer such as required by claim 1. At best, Engleson only discloses obtaining static printed information from pharmaceutical manufacturers. The proposed combination of Engleson and Vasko still lacks a drug pump manufacturer and any coordination or interaction with the drug pump manufacturer. Therefore, the combination that would result would still lack a computerized system of program code devices allowing communication and configuration among remote devices pertaining to implantable device status and maintenance, a drug pump manufacturer, and a pharmacy. Therefore, claim 1 is patentably distinct from the combination of Engleson and Vasko.

Claims 2 through 40 depend from allowable base claim 1 and, therefore, are also patentably distinct from the combination of Engleson and Vasko.

A similar argument is applicable for claims 41-74 and, therefore, claims 41-74 are patentably distinct from Engleson and Vasko.

In light of the above, applicant respectfully submits that claims 1-74 are in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

In the Office Action, the Examiner appended form PTO-892, Notice of References Cited, and therein formally cited U.S. Patent No. 5,781,442, U.S. Patent No. 5,871,465, U.S. Patent No. 5,544,661, and U.S. Patent No. 5,375,604. The Examiner informally referenced U.S. Patent No. 5,895,371 (page 19) and U.S. Application No. (2005/0021297) (page 20), but Applicant notes that these references were not formally cited in the appended form PTO-892. Applicant respectfully requests that the Examiner formally cite and acknowledge these additional references in a Notice of References Cited, in accordance with MPEP § 707.05(c).

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution. Please treat any communication filed at any time in this application requiring a petition for an extension of time under 37 CFR 1.136(a) towards timely submission as incorporating a proper petition for an extension of time and the appropriate length of time. To the extent any communication in this application are not accompanied by a payment sufficient to cover the required extension of time fees it is requested that such deficiency be charged to Deposit Account No. 06-1910.

Respectfully submitted,

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